UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 6, 2016

Subject: Efficacy Review for SaniDate 15.0
EPA Reg. No. 70299-26 (DP Barcode 434654)

From: Alison Clune
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
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To: Julie Chao / Zebora Johnson, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: BioSafe Systems, LLC
22 Meadow St.
East Hartford, CT 06108

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	10.0%
Peroxyacetic acid	15.0%
Other Ingredients	75.0%
Total	100.0%

I BACKGROUND

The product, SaniDate 15.0 (EPA Reg. No. 70299-26), is an EPA-registered food and non-food contact surface sanitizer for use on hard, non-porous surfaces in commercial environments. The registrant is requesting to add hospital disinfection claims. The registrant is submitting efficacy data from a study conducted at Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package contained a letter dated June 10, 2016 from the registrant to EPA, EPA Form 8570 (Confidential Statement of Formula), EPA Form 8570-35 (Data Matrix), 1 efficacy study (MRID 49950401), and the proposed label (dated September 21, 2016). Statements of No Data Confidentiality Claim, Good Laboratory Practice Compliance, and Quality Assurance, as well as Certificates of Analysis of the concentrations of the active ingredients for each product lot tested were included with the study.

II USE DIRECTIONS

"**GENERAL DISINFECTION**
SaniDate 15.0 is an effective one-step cleaner and disinfectant against gram positive and negative bacteria (vegetative forms): *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*. It is effective in hard water (up to 400 ppm as calcium carbonate equivalent), and in the presence of moderate organic soil. SaniDate 15.0 can be used in general commercial and medical environments to clean, disinfect, and deodorize hard, non-porous surfaces...

1. For moderately soiled surfaces a pre-cleaning step is not required. For grossly contaminated surfaces, pre-rinse surfaces and equipment to be disinfected with potable water.
2. Wash surfaces and equipment with detergent or cleaning solution to remove gross filth. Rinse with potable water to remove suspended soils and residual detergent.
3. Prepare a disinfecting solution by mixing 1.5 - 8.7 fl. oz. of SaniDate 15.0 in 5 gallons of water (393 ppm - 2300 of active peroxyacetic acid).
4. Apply the SaniDate 15.0 solution with a mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow treated surfaces to remain wet for a minimum of ten (10 minutes).
5. Rinse all treated surfaces that will contact food or commodities with potable water before use."

III AGENCY STANDARDS FOR THE PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments:
The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old or all tested batches at or below the active ingredient(s) lower certified limit(s), against a mean log density of at least 6 for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants", killing on 59 out of 60 carriers for germicidal spray testing is required to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442 within ten minutes. For AOAC Use-Dilution testing, testing for each lot should be conducted on a different day. Thus, a total of three tests for *S. aureus* and three tests for *P. aeruginosa* are necessary. Sixty carriers are required per test, without contamination in the subculture media. The performance standard for *S. aureus* is 0-3 positive carriers out of sixty. The performance standard for *P. aeruginosa* is

0-6 positive carriers out of sixty. To be deemed an effective product, the product must pass all tests for both microbes.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. **MRID 49950401 "AOAC Use-Dilution Method", by Gracia Schroeder. Bacteria: *Pseudomonas aeruginosa*, *Salmonella enterica*, *Staphylococcus aureus*. Study conducted at Accuratus Lab Services. Study completion date: 3/14/16. Laboratory Study Identification Number: A20306.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15422), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Three batches (SD1501062016 A, SD1501062016 B, SD1501062016 C) of the product, SaniDate 15.0, were tested on three separate days using Accuratus Lab Services protocol "Use Dilution Method", protocol number BSS01122315.UD, which is based on AOAC Methods 955.15, 955.14, and 964.02. The three batches of the test substance were diluted at or below the lower certified limits of the active ingredients in 400 ppm AOAC synthetic hard water. Ten (10) µL of stock culture was transferred to 10 mL synthetic broth and incubated for 24 ± 2 hours at 35-37°C. For the first daily transfer, 10 µL aliquots of culture were transferred to sufficient tubes containing 10 mL synthetic broth (without vortex mixing the *P. aeruginosa* culture). On 2/25/16 and 2/26/16, 3 and 4 additional daily transfers, respectively, were prepared. The final test culture was incubated for 48-54 hours at 35-37°C. On the day of use, the pellicle was aspirated from the *P. aeruginosa* culture and the upper portion of the culture was transferred to a sterile tube. Each test culture was vortex mixed and allowed to stand at least 10 minutes before the upper portion of the culture was removed and pooled. Twenty (20.0) mL of the *P. aeruginosa* culture, 4.0 mL of the *S. enterica* culture, and 35.0 mL of the *S. aureus* culture were diluted in 60.0 mL, 76.0 mL, and 35.0 mL synthetic broth, respectively. Each culture was adjusted to contain a 5% fetal bovine serum organic soil load. Stainless steel penicylinders were inoculated with the test organisms by immersion in the test culture suspension at a ratio of 1 carrier per 1 mL culture for 15 ± 2 minutes. Inoculated carriers were transferred to filter paper-matted petri dishes and dried for 38 minutes at 36.5-36.7°C and 50.6-52.7% relative humidity. Each carrier was exposed in separate tubes to 10 mL of the use-dilution of the test substance for 10 minutes at 19.0-21.0°C. Carriers were then transferred to tubes containing 10 mL neutralizing subculture medium (Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase) and incubated for 48 ± 2 hours at 35-37°C and stored at 2-8°C for up to 2 days before reading. Tubes were examined for the presence or absence of growth. Controls included purity, sterility, viability, neutralization confirmation (all product batches), and carrier population controls.

Note: On 2/25/16, the 3 pre-test population control carriers were dried longer than and subcultured after the test carriers for testing against *Salmonella enterica*.

V RESULTS

Disinfection – Bactericidal Efficacy (MRID 49950401)

Organism	Test Date	No. Exhibiting Growth/Total No. Tested			Average log_{10} CFU/Carrier
		SD15010620 16 A	SD15010620 16 B	SD15010620 16 C	
10 minute contact time, 1.5 oz. per 5 gallons 400 ppm hard water, 5% organic soil load					
Pseudomonas aeruginosa (ATCC 15442)	2/25/16	0/60	-	-	6.33
	2/26/16	-	0/60	-	6.65
	2/29/16	-	-	0/60	6.79
Salmonella enterica (ATCC 10708)	2/25/16	0/60	-	-	6.23
	2/26/16	-	0/60	-	6.12
	2/29/16	-	-	0/60	6.14
Staphylococcus aureus (ATCC 6538)	2/25/16	0/60	-	-	6.25
	2/26/16	-	0/60	-	6.39
	2/29/16	-	-	0/60	6.34

VI CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, SaniDate 15.0, as a disinfectant with bactericidal activity on hard, non-porous surfaces when diluted at 1.5 oz. per 5 gallons of 400 ppm hard water in the presence of a 5% organic soil load for a 10 minute contact time against the following bacteria:

   Pseudomonas aeruginosa (ATCC 15442) MRID 49950401
   Salmonella enterica (ATCC 10708) MRID 49950401
   Staphylococcus aureus (ATCC 6538) MRID 49950401

   According to the analysis of the active ingredient concentration for each product batch, the tested dilutions were at or below the lower certified limit of the active ingredient. Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the test organisms.

VII LABEL

Note to PM: Page numbers refer to redline label (V5) dated September 21, 2016.

1. The proposed label claims that the product, SaniDate 15.0, is an effective health care disinfectant on hard, non-porous surfaces when diluted at 1.5 oz. per 5 gallons of water with a 10 minute contact time against the following bacteria:

   Pseudomonas aeruginosa (ATCC 15442)
   Salmonella enterica (ATCC 10708)
   Staphylococcus aureus (ATCC 6538)

   These claims are **acceptable** as they are supported by the submitted data.

2. Throughout the directions for use, the active ingredient concentration in ppm should be given for both active ingredients.

3. On page 3 of the proposed label, in the fogging instructions for non-public health microorganisms, "100%" should be removed from the dilution rate of "85-100 ppm 100% peroxyacetic acid in the use solution."

4. On pages 5-6 of the proposed label, in the directions for use for sanitizing conveyors, peelers, etc., final sanitizing bottle rinse, and sanitizing of casing or shell eggs and hatching eggs, the required contact time of 1 minute should be specified.

5. On page 7 of the proposed label, in the directions for use for sanitization of hard, non-porous, non-food contact surfaces, the first sentence should be changed to "SaniDate 15.0 is an effective hard, non-porous, non-food contact surface sanitizer..."

6. On pages 7 and 11 of the proposed label, the directions for "Foam Applications" should be removed or revised such that no chemical foaming agents will be used to prepare the foam. To support these use directions, the product would need to be tested in the presence of a specific chemical foaming agent, and the agent would need to be specified on the label. If the foaming application instructions remain on page 12, the use dilution (0.3 fl. oz. of SaniDate 15.0 per gallon of water, or equivalent dilution) and required contact time of 10 minutes should be specified.

7. On page 7 of the proposed label, in the directions for use for "General Disinfection", the ATCC numbers of the tested strains of the organisms should be included in the organism list.

8. On pages 7-8 of the proposed label, in the directions for use for "General Disinfection", "moderate organic soil" and "moderately soiled" should be changed to "light organic soil" and "lightly soiled", or a similar phrase such as "surfaces that are not visibly soiled." The 5% soil load is meant to represent soil that is not easily visible.

9. On page 8 of the proposed label, in the directions for use for "Disinfecting Pharmaceutical and Cosmetic Surfaces", the application method and contact time should be specified.

10. On page 9 of the proposed label, in the directions for use for "Tractor Trailer and Transportation Vehicles Disinfection", "fungus and mold" should be removed. Data was not submitted to support a fungicidal claim. The last statement before the numbered directions should be changed to "...to prevent the cross contamination of bacteria from treated surfaces."

11. On page 10 of the proposed label, in the directions for use for foot baths, "cross contamination from area to area" should be changed to "cross contamination from treated surfaces."

12. On page 11 of the proposed label, the directions "To Fog Dairy, Beverage, Food Storage Facilities, Packing Houses and Food Processing Plants" as an adjunct to acceptable manual cleaning and disinfecting should be removed. This use is not acceptable per the Agency letter dated Apr 01 2013 available from https://www.epa.gov/pesticide-registration/fogger-and-mister-final-signed-letter.